

**Department of Health and Human Services**

**§ 160.414**

(c) The degree of culpability of the covered entity, including but not limited to:

(1) Whether the violation was intentional; and

(2) Whether the violation was beyond the direct control of the covered entity.

(d) Any history of prior compliance with the administrative simplification provisions, including violations, by the covered entity, including but not limited to:

(1) Whether the current violation is the same or similar to prior violation(s);

(2) Whether and to what extent the covered entity has attempted to correct previous violations;

(3) How the covered entity has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the covered entity has responded to prior complaints.

(e) The financial condition of the covered entity, including but not limited to:

(1) Whether the covered entity had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the covered entity to continue to provide, or to pay for, health care; and

(3) The size of the covered entity.

(f) Such other matters as justice may require.

**§ 160.410 Affirmative defenses.**

(a) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violations, including the following:

(1) The violation is an act punishable under 42 U.S.C. 1320d-6;

(2) The covered entity establishes, to the satisfaction of the Secretary, that it did not have knowledge of the violation, determined in accordance with the federal common law of agency, and, by exercising reasonable diligence, would not have known that the violation occurred; or

(3) The violation is—

(i) Due to reasonable cause and not willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or by exercising reasonable diligence would have known, that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

(b) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violations, including the following:

(1) The violation is an act punishable under 42 U.S.C. 1320d-6; or

(2) The covered entity establishes to the satisfaction of the Secretary that the violation is—

(i) Not due to willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

[74 FR 56131, Oct. 30, 2009]

**§ 160.412 Waiver.**

For violations due to reasonable cause and not willful neglect that are not corrected within the period described in § 160.410(a)(3)(ii) or (b)(2)(ii), as applicable, the Secretary may waive the civil money penalty, in whole or in part, to the extent that the payment of the penalty would be excessive relative to the violation.

[74 FR 56131, Oct. 30, 2009]

**§ 160.414 Limitations.**

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with § 160.420, within 6 years from the date of the occurrence of the violation.